

REMARKS

Claims 1-41 are pending in the present application. In the Office Action dated March 10, 2004, the Examiner rejected claims 1-36 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner further rejected claims 1, 2, 4, 5, 14, 15, 17, and 22 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,503,559 to Vari ("Vari"). Claims 1, 2, 4, 14, 15, 17 and 22-24 are also rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,326,263 to Weissman ("Weissman"). Claims 1, 4-7, 12, 14, 17, 18, 20 and 22-24 are further rejected under 35 U.S.C. §102(b) as anticipated by WO 98/11842 to Billet, *et al.* ("Billet"). Claims 3, 5 and 16 are rejected under 35 U.S.C. §103(a) as unpatentable over the Weissman reference. Claims 6-8 and 18 are also rejected under 35 U.S.C. §103(a) as unpatentable over the Weissman reference in view of the Billet reference. Claims 2, 3, 8, 15 and 16 are further rejected under 35 U.S.C. §103(a) as unpatentable over the Billet reference alone. Finally, claims 1-8, 12, 14-18, 20, 22, 23, 25, 27-32 and 34-36 are rejected under 35 U.S.C. §103(a) as unpatentable over EP 0 938 875 to Martelli, *et al.* ("Martelli") in view of the Billet reference. Claims 37-41 are allowed. Claims 9-11, 13, 19, 21, 26 and 33 would be allowable if rewritten in independent form, provided that the rejections under 35 U.S.C. §112, first paragraph are fully addressed.

The Examiner is thanked for his careful review of the present application and for his indication of allowable subject matter. Applicant nevertheless disagrees with the stated grounds of rejection and desires to further clarify various distinctions of the applicant's invention over the cited art. Reconsideration of the present application is therefore requested in light of the present amendment and following remarks.

The disclosed embodiments of the invention will now be discussed in comparison to the prior art. It is understood, however, that the discussion of the disclosed embodiments, as well as the discussion of the differences between the disclosed embodiments of the present invention and the prior art do not define the scope or interpretation of any of the claims. Instead, such discussed differences, when presented, are offered merely to help the Examiner appreciate important claim distinctions as they are discussed.

The various embodiments of the present invention are directed to an apparatus and methods for obturating a root canal of a tooth. In one embodiment, a plug is disclosed that is

configured to be implanted into the root canal. The plug may be comprised of an optically transmissible, polymeric material of uniform composition that is in a fully polymerized state before the plug is implanted into the root canal. The plug is suitably sized and shaped so that the plug substantially occupies a volume of the endodontically-prepared root canal passage following implantation of the plug into the root canal (as shown, *inter alia*, in Figure 3 of the present application). The plug also extends at least proximately to the apical foramen of the root canal, and is sealably secured to the walls of the root canal by an adhesive material that may be applied to the walls, or to the plug before insertion into the canal so that the adhesive is interposed between the plug and the walls when the plug is inserted into the canal (page 10, lines 20-25). The adhesive may include selected photocatalysts that cause the adhesive to polymerize upon exposure to light of a selected wavelength, so that the plug is sealably secured in the canal (page 11, lines 10-15). In other embodiments, the plug may form a portion of a two-part bonding system. Accordingly, the plug may constitute a catalyst portion, while the adhesive forms a corresponding resin portion of the bonding system. Alternately, the plug may form the resin portion, while the adhesive forms the catalyst portion (page 12, lines 11-20). In this embodiment, the plug may be formed from a material that is not optically transmissible, since the plug is secured to the walls of the root canal by a reaction between the catalyst and the resin.

In another embodiment of the invention, a carrier is disclosed that includes a plug portion that is comprised of an optically transmissible, polymeric material of uniform composition that is in a fully polymerized state before the plug is implanted into the root canal. The carrier further includes a support portion coupled to the plug portion that permits the plug portion to be conveniently manipulated while the implantation process is occurring. The plug portion of the carrier extends to the apical foramen of the root canal, and also occupies substantially the entire volume of the endodontically-prepared root canal (as shown in Figure 9). The plug portion is also sealably secured to the walls of the root canal by an adhesive material that is comprised of selected photocatalysts that cause the adhesive to polymerize upon exposure to light of a selected wavelength. Alternately, the bonding methods described more fully above may also be used. Following the implantation of the plug portion of the carrier into the root canal, the support may be severed from the plug portion (as shown in Figure 11).

The Examiner cites the Vari reference as pertinent to the patentability of claims in the present application. Specifically, the Examiner cites Figure 20 and associated descriptive matter in columns 9 and 10 of the Vari reference for disclosing an optical fiber that may be inserted into the root canal of a tooth, and extended downwardly to the apical portion of the tooth. Referring in particular to Figure 20, the disclosed apex locator 94 includes an optical fiber that may be extended to the apex 34 of the tooth 10, but the optical fiber does not substantially abut the walls of the root canal, nor does it substantially occupy an entire volume of the root canal, as clearly shown in Figure 20. Instead, the locator 94 contacts only a portion of the wall as it is inserted and moved inwardly to the apex 34. In other embodiments, as shown in Figure 21, Vari discloses an apex sealing apparatus 96 that includes a plunger 98 that is coupled to a tube 100, and an optical fiber 102. The tube 100 and the optical fiber 102 extend downwardly into the root canal to the apex 34 (col. 9, lines 64-65). The plunger 98 is used to force a light cure restorative into through the tube 100 and into the canal. The light cure restorative is then cured by transmitting light to the restorative material through the optical fiber 102 (col. 9, line 67 bridging to col. 10 lines 1-4). With respect to this embodiment, the optical fiber cannot substantially abut the walls of the root canal, nor can it substantially occupy an entire volume of the root canal since both the tube 100 and the optical fiber 102 must both be accommodated within the root canal space simultaneously.

The Examiner further cites the Weissman reference. Weissman discloses an apparatus and method for reinforcing an endodontically prepared tooth. With reference to Figure 1 of the Weissman reference, a post tool and curing element 11 is inserted into the root canal to contact a mass of gutta percha 12 that has been previously condensed into the apical portion of the tooth (*i.e.* the root canal treatment has already been completed prior to the implementation of the Weissman invention). The tooth canal wall is then sealed by forming a casement 16 consisting of a composite filler and a crown amalgam seal 16a (col. 6, lines 4-18). The disclosed post tool and curing element 11 does not extend to the apical portion of the tooth. Instead, the element 11 extends, at most, to an upper surface of the condensed gutta percha 12, which is “at least about 4 mm” in depth (col. 6, line 13). Furthermore, the casement 16 is interposed between the post tool and curing element 11 so that the element 11 does not substantially abut the wall of the root canal.

The Examiner also cites the Billet reference. Billet discloses an insert for filling a dental canal. The disclosed insert is comprised of a semi-rigid and malleable core that is formed from a material in a fully polymerized state that is coated with one or more first sleeves formed by a paste of a composite material in a pre polymerization state (col. 3, lines 10-13 and col. 3, lines 49-53). The one or more sleeves are retained by a sheath, which also consists of a composite material in the pre-polymerization state (col. 3, lines 65-66). Although Billet discloses that the sheath encloses "...any sort of fibre...allowing electromagnetic radiation to pass..." (col. 3, lines 29-33), it is noted that the fibers are positioned in the core portion of the insert, which is spaced apart from the enclosing sheath, which abuts the walls of the root canal. The Examiner is directed in particular to Figure 3 of the Billet reference, which shows the pre-polymerized sheath 15 enclosing the core 10. Accordingly, Billet fails to disclose or to fairly suggest that any portion of the insert that substantially abuts a wall of the root canal is in a fully polymerized state.

Finally, the Examiner has cited the Martelli reference. Martelli discloses a dental prosthesis support that may be inserted into an endodontically prepared tooth. In particular, the dental prosthesis support includes a pin formed from a transparent material that may be inserted into the root canal of the tooth. With reference now to Figure 4, the pin 6 is positioned in the tooth 3, and is substantially enclosed by a composite material 10. In particular, the applicant notes that the pin 6 does not substantially abut the walls of the root canal, and that the pin 6 does not fully extend to the apex of the root canal. Instead, a filler material (presumably gutta percha, or other conventional materials) is implanted into the apex, as shown in Figure 4. Applicant notes that before the Martelli invention is implemented, the root canal procedure has been completed. Applicant therefore respectfully asserts that Martelli fails to disclose or fairly suggest a plug that substantially abuts the walls of the root canal that extends to the apical portion of the tooth.

Turning now to the claims, differences between the claim language and the applied art will be specifically pointed out. Claim 1, as amended, recites in pertinent part: "A plug for implantation into an endodontically prepared root canal of a tooth comprising...an elongated body...having a distal end and a proximal end and having a length to allow the distal end to be positioned adjacent to an apical portion of the tooth when the body is inserted in the

root canal of the tooth, *the body being further suitably proportioned to substantially abut the walls of the root canal of the tooth and extend to the apical portion of the root canal when implanted, the plug being further comprised of a material that is optically transmissive and fully polymerized prior to insertion into the root canal of the tooth.* (Emphasis added). The Vari reference does not disclose or suggest this. Instead, Vari discloses an optical fiber does not substantially abut the walls of the root canal. The Weissman reference also fails to disclose or suggest this. Instead, Weissman discloses a post tool that does not extend to the apical portion of the tooth. Furthermore, the post tool extends, at most, to an upper surface of a condensed gutta percha mass, so the post tool fails to extend to an apical portion of the tooth. A casement is interposed between the post tool so that the tool does not substantially abut the wall of the root canal. Finally, the Billet reference does not disclose or suggest this. Billet discloses an insert having a core portion in a fully polymerized state that is surrounded with one or more sleeves formed by a paste of a composite material in a pre polymerization state. In particular, the outer sheath that abuts the walls of the root canal is comprised of a material in the pre-polymerized state. Claim 1 is therefore allowable over the Vari, Weissman and Billet references. Claims depending from claim 1 are also allowable based upon the allowable form of the base claim and further in view of the additional limitations in the dependent claims.

Claim 14, as amended, recites in pertinent part: “A carrier for root canal obturation in an endodontically prepared tooth comprising...an elongated plug portion comprised of a biologically implantable, resilient material having a distal end and a proximal end and having a length to allow the distal end to be positioned adjacent to an apical portion of the tooth when the plug portion is implanted in the root canal of the tooth, *the distal end extending to the apical portion and substantially abutting the walls of the root canal when the plug is implanted, the plug portion being further comprised of a material that is optically transmissive and fully polymerized prior to insertion into the root canal of the tooth...*” (Emphasis added). Again, as explained more fully above, the Vari, Weissman and Billet references do not disclose or suggest this. Accordingly, claim 14 is allowable over the cited references. Furthermore, claims depending from claim 14 are also allowable based upon the allowable form of the base claim and further in view of the additional limitations in the dependent claims.

Claim 25, as amended, recites in pertinent part: “A method for obturating a root canal passage in a tooth, comprising...applying a light-curing adhesive to the root canal passage...implanting an optically transmissive plug into the root canal passage, *the plug being in a fully polymerized condition prior to implanting the plug into the root canal passage, the plug abutting surfaces of the root canal passage and extending to an apical portion of the root canal when implanted...*” (Emphasis added). The Martelli and Billet references do not disclose this, either singly or in combination. Martelli discloses a fully polymerized post, but it fails to abut the surfaces of the root canal passage. Billet discloses a fully polymerized core portion, which is enclosed by a sheath in a pre-polymerized state. Furthermore, the motivation to combine the cited references must be taught in at least one of the applied references. In this case, the Billet reference is silent regarding the advantage of extending the disclosed insert to the apical portion of the tooth. Accordingly, claim 25 is allowable over the cited references. Claims depending from claim 25 are similarly allowable based upon the allowable form of the base claim and further in view of the additional limitations in the dependent claims.

Finally, claim 32, as amended, recites in pertinent part: “A method for obturating a root canal passage in a tooth, comprising...applying an adhesive to the root canal passage...inserting an optically transmissive plug into the root canal passage, *the plug being in a fully polymerized condition prior to inserting the plug into the root canal passage and extending to an apical portion of the root canal, the plug abutting surfaces of the root canal passage...*”. (Emphasis added). Again, the Martelli and Billet references do not disclose this, either singly or in combination. Claim 32 is therefore allowable over the cited references. Claims depending from claim 32 are also allowable based upon the allowable form of the base claim and further in view of the additional limitations in the dependent claims.

With regard to the Examiner’s rejection of claims 1-36 under 35 U.S.C. §112, first paragraph, applicant respectfully submits that the portions objected to have been removed. Specifically, the recitation that the “plug seals the apical portion” has been altered to recite that the plug *extends* to the apical portion of the tooth. Applicant therefore respectfully requests that the rejections under 35 U.S.C. §112, first paragraph, be removed.

With regard to the Examiner's claim rejections under 35 U.S.C. §103(a), applicant respectfully submits that the foregoing amendments also overcome the Examiner's rejections under 35 U.S.C. §103(a).

Finally, claims 42 through 91 are new. No new matter has been introduced through the addition of these claims.

Respectfully submitted,

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MAIL CERTIFICATE

I hereby certify that this communication is being deposited with the United States Postal Service via first class mail under 37 C.F.R. § 1.08 on the date indicated below addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sept. 10, 2004
Date of Deposit

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